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Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932				BARHAM, BETHANY P
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/721,652	GIBSON ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 July 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,6-8,10,11,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,6-8,10,11,26 and 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Summary

Receipt is acknowledged of the Applicants' Response and Amended Claims filed on 7/29/09. Claims 1, 6-8, 10-11, and 26-27 are pending in this action. Claims 1, 6-8, 10-11, and 26-27 are rejected.

Due to Applicant's claim amendments the previous rejection drawn to claim 27 is hereby amended.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6-8, 10-11 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4) of fiber from GOS and FOS, does not reasonably provide enablement for about 15 to about 20 g. (instant claim 1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to use this

invention at the higher claimed range of about 15 to about 20 g. without undue burden. This is a scope of enablement rejection.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The instant claim 1 is directed to “a composition comprising an oligosaccharide blend that comprises fructo-oligoasaccharide (FOS) and galacto-oligoasaccharide (GOS), wherein (a) the composition comprises from about 15 to about 20 g of the oligosaccharide blend; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.” It is the examiner’s position that the use of this claim is not supported by the instant specification, and that the scope supported by the specification includes 2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4) of fiber (FOS and GOS) in a single composition.

The nature of the invention: The instant invention is directed to a “a composition comprising an oligosaccharide blend that comprises fructo-oligoasaccharide (FOS) and galacto-oligoasaccharide (GOS), wherein (a) the composition comprises from about 15 to about 20 g of the oligosaccharide blend; (b) each of said oligofructose and oligogalactose are composed of chains with a degree of polymerization ranging from about 2 to about 7; (c) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (d) the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.”

The state of the prior art: As set forth in 6,399,124 ('124), the fiber content of a single composition can provide up to a maximum of 10g of fiber (FOS, GOS, mixtures thereof) per dessert and that higher quantities in a dessert leave an unpleasant feeling of heaviness in the stomach (col. 5, lines 24-29; claims 1-2). The art teaches that a single composition should not contain more than 10 g of fiber. With a broad general disclosure, Applicants have not provided a basis for how their invention would specifically work and be useful at the higher claimed limit of about 15g to about 20g of fiber. It is clear from the prior art above that use in a single composition above 10g give discomfort to a person. Given the instant disclosure, one of ordinary skill in the art would have to resort to trial and error experimentation in order to use the invention commensurate in scope with the claims.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention is capable of being useful at an amount higher than the 9.86g of Example 3. Guidance for using or preparing a composition at the higher instant claimed values is not provided. As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a substantial gap between a useful composition comprising 2g, 2.5g, 9.86g and one comprising about 15g to about 20g. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: Guidance for preparing a compositions comprising 2g, 2.5g, and 9.86g of fiber in Examples in the instant specification is provided. There are no examples provided of how one would use a composition of an amount above 10g, and certainly not 20g or even 15g and as such use of these amounts is not supported.

The quantity of experimentation: In the instant case, there is a substantial gap between a composition comprising 2g, 2.5g, and 9.86g fiber or about 20g, the specification is not supportive of the entire instant claimed range of about 15g to 20g of fiber. Consequently, a burdensome amount of research would be required by one of

ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments beyond 2g, 2.5g, and 9.86g of fiber would be useful in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

NEW REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesens et al US 6,399,124 B1 in view of Van Leeuwen et al US 2003/0138476 A1.

The instant claims are drawn to a composition comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein each of said FOS and GOS contains up to 95%

by weight of said oligofructose and said oligogalactose that are composed of chains with a degree of polymerization ranging from about 2 to about 7 and wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of Lactobacilli, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties.

- Lesens et al teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream for the treatment and/or prevention of gastrointestinal disorders, for strengthening the immune system, or for increasing the absorption of minerals (abstract) (according to the limitation of claim 27).
- Lesens et al teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen for example from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc (col. 4, lines 44-47; and claim 2) (according to the limitation of claim 27).
- The preferred galacto-oligosaccharides comprise a saccharide part consisting of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory which may comprise, for example, 1-9 repeating units (col. 4, lines 56-64; and claim 26). Examples 1, 4 and 5 specifically teach edible compositions, coatings and decorations containing galactooligosaccharide P7L, Raftilose L30 and Actilight 950P. (wherein these are the limitations of claim 27)

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- Examples 4-5 of Lesens et al teach a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition (according to the limitation of instant claim 27).
- Note the property or function of promoting lactic acid bacteria by ingestion of FOS and GOS are not separable from the structure of FOS and GOS as taught by Lesens et al.
- Lesens does not teach.

Lesens et al does not teach a composition comprising glutamine or an oligosaccharide blend that “consists essentially of” FOS and GOS, but the prior art does teach compositions comprising FOS and GOS and does not teach that the other components of the composition alter the effectiveness of FOS and GOS including glutamine and does teach compositions containing milk, animal or vegetable proteins, which are known to contain glutamine.

- Van Leeuwen et al teach nutritional preparations such as baby food or enteral food (abstract) which include prebiotics such as fructo-oligosaccharides and galacto-oligosaccharides and further glutamine or an equivalent such as is known in the art (pg. 1, [0013-0014], pg. 2, [0017]). Further, Van Leeuwen et al claims a nutritional preparation as a nutritional preparation with also contains glutamine or equivalent thereof and further prebiotics such as galacto-

oligosaccharides and fructo-oligosaccharides (claims 1-3, 8, and 12) (meeting the limitation of instant claim 26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compositions as taught by Lesens et al with glutamine as taught by Van Leeuwen et al. One of ordinary skill in the art would have been motivated to combine the teachings since both teach nutritional compositions that help the intestinal tract and provide fibers such as prebiotics (galacto-oligosaccharides and fructo-oligosaccharides). As such one would have a reasonable expectation of success in adding the glutamine of Van Leeuwen et al to the compositions of Lesens et al, especially since Van Leeuwen et al teaches that products which are rich in glutamine include vegetable proteins (pg. 1, [0005]), as is already taught by Lesens et al (claim 9).

Further it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to Lesens et al to make a composition of FOS and GOS in a specific ratio, and one of ordinary skill in the art would be motivated to experiment and optimize values to obtain workable ranges. As stated in MPEP 2144.05: “[W]here the general conditions of a claim are disclosed in prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” The skilled artisan would know how to optimize the amounts taught by Lesens et al to obtain the optimal gastrointestinal benefit, since Lesens et al teaches a composition of fibers wherein the fibers are preferably FOS and GOS and teaches various examples comprising both and a single serving of up to 10g of fiber.

Response to Arguments

Applicant's arguments with respect to claims 1, 6-8, 10-11 and 26-27 have been considered but not persuasive. Applicants argue that the claims are fully enabled by the specification and that no burdensome amount of experimentation to make and use for the skilled artisan is required and that the Examiner has confused enablement with written description (response pg. 6 and 8). Applicants argue that support for 20g or 15g of oligosaccharide blend is provided in [0040] and that any skilled artisan would be capable of measuring that amount and adding the blend to a composition (response pg. 6 and 8). The Examiner respectfully points out that 'measuring' 20g or 15g of fiber is not at issue as the enablement rejection at issue is solely based on "use this invention at the higher claimed range of about 15 to about 20 g. without undue burden" and the disclosure of the amount for 20g or 15g of oligosaccharide blend does not render that amount "useful" or capable of being "used", especially when the prior art teaches against "using" such an amount since it results in bad side effects. Applicants also argue that enablement does not "require that administration of a composition results in no adverse side effects...many patented drugs...cause adverse side effects" (response pg. 8). However the Examiner respectfully points out that each and every application is considered on its own merits and the fact that other patents have drugs that "can cause adverse side effects" is not pertinent to this case, what is pertinent is that the prior art '124 teaches that a composition above 10g of fiber is not useful.

Applicant's also repeatedly state that an example may be "working" or "prophetic" and a "prophetic example describes an embodiment of the invention based on predicted

results rather than work actually conducted or results actually achieved". The Examiner respectfully points out that the prior art of record '124 teaches the fiber content of a single composition can provide up to a maximum of 10g of fiber (FOS, GOS, mixtures thereof) per dessert and that higher quantities in a dessert leave an unpleasant feeling of heaviness in the stomach (col. 5, lines 24-29; claims 102). The art teaches that a single composition should not contain more than 10 g of fiber and Applicant instant Examples do not contain more than 10 g of fiber (2 g. (Example 2), 9.86g (Example 3), and 2.5g. (Example 4)). The burden is on Applicant to show how the composition would be used at the higher amounts of about 15-about20 g. when the prior art teaches adverse effects, a showing of factual evidence or a side-by-side comparison that a single serving containing greater than 10g (i.e. about 20g of fiber) does not produce 'an unpleasant feeling of heaviness in the stomach'.

Applicants argue that Lesens et al does not teach compositions of glutamine and "consisting essentially of" fiber of FOS and GOS mixture (pg. 10-11) and that the prior art does not teach 'about 15g to about 20 g' of fiber. The Examiner respectfully points out that the instant claim 27 is not drawn to 'about 15g to about 20 g' of fiber and as such Applicant is arguing limitations not in the instant claim. Further the rejection of record has been amended to include Van Leeuwen et al which teaches oligosaccharides such as GOS and FOS with glutamine and in combination with Lesens et al teach both galacto-oligosaccharides and fructooligosaccharides are preferred and claims "mixtures thereof" (col. 4, lines 56-64; and claim 26). Claim 27 with the language 'consisting essentially of' does not overcome the prior art of record and is treated as

'comprising' since Applicant does not provide evidence that additional components would materially change the characteristics of the instant invention. As the MPEP 2163 states: "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F3.d 1234, 1239-1240, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also MPEP § **2111.03**. The claim as a whole, including all limitations found in the preamble (see Pac-Tec Inc. v. Amerace Corp., 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention)), the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement. An applicant shows possession of the claimed

invention by describing the claimed invention with all of its limitations. Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Applicant also argues that the prior art does not teach synergistic effect of FOS and GOS, however Lesens et al and Van Leeuwen et al do teach that the edible composition containing the fibers (FOS and GOS) and glutamine promote the growth of the lactic acid bacteria in a human intestinal tract (Lesens abstract, claim 1; Van Leeuwen claims 1-3, 8, and 12) and as such proves that these fibers enhance lactic acid bacteria growth. The property or function of promoting lactic acid bacteria by ingestion of FOS and GOS are not separable from the structure of FOS and GOS as taught by Lesens et al. Simply because Lesens or Van Leeuwen is silent to the synergism of FOS and GOS does not take away from the fact that the art teaches FOS, GOS are preferred and mixtures thereof, since the prior art teaches a composition and process for forming said composition described by applicants instant application, but applicants observation that it also has 'synergistic effect' does not give it patentable weight, since it is the same composition and same process of making, as adding a characterization to a prior art patented invention is not patentable.

Conclusions

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BETHANY BARHAM whose telephone number is (571)272-6175. The examiner can normally be reached on M-F from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bethany Barham
Examiner 1615

/Robert A. Wax/
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